UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

Addendum: August 10, 2020
Original Review Date: November 07, 2019

MEMORANDUM

Subject: Efficacy Review for Concrobium Mold Control; EPA File No. 82552-G; DP Barcode: D454099; Submission #: 1036690; E-Sub # 40557.

From: Ibrahim Laniyan, Ph.D.
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Date signed: 8/10/2020

To: Jacqueline Hardy RM 34/ Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Siamons International, Inc.
48 Galaxy Blvd., Unit 413
Toronto, Ontario M9W 6C8
Canada

Formulation from the Label:

Active Ingredients	% by wt.
Sodium Carbonate	1.005 %
Other Ingredients:	98.995 %
Total	100.000 %

I. BACKGROUND

Product Description (as packaged, as applied): Liquid RTU.

Submission type: New end use product

Currently registered efficacy claim(s): NA

Requested action(s): New product Registration

Documents considered in the original review (dated November 7, 2019):

- Letter from applicant to EPA dated June 26, 2019
- Application for Pesticide (EPA form 8570-1) dated June 26, 2019
- Confidential Statement of Formula (EPA form 8570-4) dated June 26, 2019
- Certification with Respect to Citation of Data (EPA Form 8570-34) dated June 26, 2019
- Data Matrix (EPA Form 8570-35) dated June 26, 2019
- 5 efficacy studies (MRID nos. 501633-01 - 501633-09)
- Proposed label dated 05/26/2019.

New documents considered:

- Spray Volume Collection Data (dated 2/28/2020)
- Visual photographs and video were submitted 2/28/2020
- Proposed label, dated 4/20/2020

Per the original review dated November 7, 2020, the submitted studies did not support use of the product as a ready to use spray on precleaned hard nonporous surfaces for the following claims due to testing using 15 sprays (excessive and not representative of typical use application):

- Disinfectant against: *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442)
- Fungicide against *Trichophyton interdigitale* (ATCC 9533)
- Mildewcide against *Aspergillus niger* (ATCC 6275)
- Mildew/Fungistat against: *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333)

In a follow-up discussion, the company shared that the spray nozzle used during testing released less product per spray than a typical competitor trigger spray nozzle. EET expressed end user compliance concerns with utilizing a nozzle which requires an excessive number of sprays to achieve wetness. As a path forward, the company proposed to swap out the spray nozzle on bottle to high volume trigger sprayer nozzles and provide comparative volumetric data and visuals to demonstrate:

a) the amount of product released by the 15 sprays (0.8 g) of the original nozzle is approximately equivalent to a typical competitor trigger spray (reported as 0.7 g using 4 sprays)

b) the amount of product released by 4 sprays of the new nozzles (1 g and 1.7 g) is equal to or greater than the volume released by 15 sprays (0.7 g) from the original nozzle.

II. CONCLUSIONS

The comparative spray volume data in combination with the submitted efficacy studies **support** use of the product, Concrobium Mold Control (EPA File No. 82552-G) as a ready-to-use liquid spray using the high volume spray nozzles, on precleaned hard nonporous surfaces for the following claims:

- Disinfectant against: *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442)
- Fungicide against *Trichophyton interdigitale* (ATCC 9533)
- Mildewcide against *Aspergillus niger* (ATCC 6275)
- Mildew/Fungistat against: *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333)

III. LABEL COMMENTS

Proposed Label dated 04/20/2020

Note to PM: Label concentrations should be revised to match the CSF.

a. Throughout the label,
   i. qualify each instance of “eliminate[s]”, “eliminate”, “get rid of”, “wipe out” or similar with “99.9%” where associated with public health claims. The standalone claim implies enhanced efficacy / complete kill.
   ii. qualify each instance of “stops”, “prevents”, or “inhibits” mold and mildew with “for 7 days” as supported by data.
   iii. remove “break the mold”, “fight mold”, “defend”, and “attack” as this is inaccurate/misleading regarding the activity of the product.
   iv. qualify claims for soft surfaces (e.g. fabrics, upholstery, curtains, etc) with “cotton” as supported by the data.
b. On page 1, remove “spray [n’] [and] [go]” as this is misleading. The directions for use require a 10-minute contact time to achieve efficacy.
c. On pages 2 and 4, remove “[All]-in one [solution]” as this claim is overly broad and implies enhanced efficacy.
d. On page 5,
   i. remove “[Powered] [by]” or qualify this claim for cleaning only as this claim implied enhanced efficacy.
   ii. remove “just spray [and] [go] [walk away]” as this is misleading. Per the directions for use, a 10-minute contact time should be observed to ensure efficacy.
e. On page 7, remove brackets around “[glazed]” and “[sealed]” as these qualifiers are not optional.
f. On page 9,
   i. remove claims for “[moist] [humid] [and] [or] [wet] environments” as this is not supported by testing.
   ii. revise “heavy soil” to “visible soil”
   iii. product was tested as a spray; remove directions for use for all other application types.
g. On page 11, revise reapplication instructions to specify “reapply weekly or sooner, when growth or odor reappears.”